## SUMMARY OF THE ON-SITE ASSESSMENT COMMITTEE MEETING FEBRUARY 2, 2001

The On-site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on Friday, February 2, 2001, at 1:00 p.m. Eastern Standard Time (EST). The meeting was led by its chair, Mr. William Ingersoll of the U.S. Navy. A list of action items resulting from the meeting is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to discuss Appendix B-2 and to address items of importance as summarized in the previously distributed meeting agenda*.

#### INTRODUCTION

After a welcome of participants, Mr. Ingersoll informed the committee that the meeting's primary subject for discussion would be the most recent revision of Appendix B-2 as electronically distributed shortly before the meeting by Mr. David Friedman.

#### APPENDIX B-2

The committee reviewed Appendix B-2 paragraph-by-paragraph. There was some discussion of the use of the words "assessment," "audit," and "review." Ms. Marlene Moore noted that there are international definitions for "assessment" and "audit" that define different intents. She offered to distribute ISO Guide 2 to committee members so that the committee can define each word and use it appropriately.

There was moderate discussion of critical test method elements. A key point made by participants was that what is critical to one individual versus what is critical to another individual is always a matter of opinion. Mr. Friedman explained that this is why he keyed his revision of Appendix B-2 to the needs of the project. This led participants to question whether the needs of the project override the needs of NELAC or the needs of the method.

It was noted that laboratory deviations from standard operating procedures (SOP) directives must still address critical test method elements. In subsequent discussion the committee identified two different potential situations of laboratory deviations - the deviation of the analyst from the SOP and the deviation of the SOP from the reference method. While the committee was in agreement that laboratory deviations must pass an internal management approval process, they also noted that any deviation must be scientifically valid. A laboratory must have some procedure that documents when a deviation must be tested to demonstrate that it meets the quality system requirements for modifications to methods. Such an initial demonstration of capability should be part of the laboratory's quality system.

There was moderate discussion of biological tests and of the inclusion of references to animal study species in the critical elements that must be examined for each test method.

There was moderate discussion of the inclusion of matrix interference checks for project-specific quality control (QC) procedures. A participant noted that an assessor must always answer two questions. Is the method in control for a clean material, and does the laboratory know how to apply that method to the analysis of its project-specific samples? In response Mr. Friedman explained that the intent of his organization of Appendix B-2 had been to describe an initial demonstration of capability followed by a continuing demonstration that the system is in control. He suggested that, although standards may change, such generic guidelines need never change.

The committee made minor editorial comments which Mr. Friedman incorporated into the document during the meeting. Before the meeting ended Mr. Friedman distributed the revised document to all committee members via electronic mail. It was agreed that committee members who had been unable to participate in the teleconference should have the opportunity to review the revised appendix.

#### APPENDIX B-1

Noting its references to technology audits, Ms. Moore suggested that Appendix B-1 is potentially problematic. The committee was in agreement that insufficient time remained to discuss the appendix in this teleconference. The committee flagged Appendix B-1 as a discussion topic for the next teleconference.

#### MISCELLANEOUS BUSINESS

It was noted that the last On-site Assessment Committee meeting minutes posted on the NELAC Website are those for the committee's October 31, 2000, face-to-face meeting at the Sixth NELAC Interim Meeting (NELAC 6i). The committee requested that Research Triangle Institute (RTI) staff track the status of their meeting minutes.

### **CONCLUSION**

The allotted time for the teleconference having expired, the meeting was adjourned at 2:30 p.m. EST. The committee's next meeting will be on Wednesday, February 14, 2001, via teleconference.

## ACTION ITEMS ON-SITE ASSESSMENT COMMITTEE MEETING FEBRUARY 2, 2001

Item No.	Action	Responsible Member	Date to be Completed
1.	Committee will review revised Appendix B-2.	All	02/14/01
2.	Committee will reference ISO Guide 2 for international definitions of "ausit," "assessment," and (if applicable) "review."	M. Moore to e-mail guide to committee	02/14/01
3.	Committee will place Appendix B-1 on its agenda for discussion during 02/14/01 teleconference.	All	02/14/01
4.	RTI will track web status of committee's meeting minutes.	L. Greene, G. Tatsch	02/09/01

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